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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MICHAEL T. LOTZE and HIDEAKI TAHARA

Appeal 2009-015385
Application 10/688,845
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and ERIC GRIMES, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134 involving claims to a therapeutic composition. The Examiner has rejected the claims as

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

anticipated by the prior art. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 27-29, 31, 35-38, and 40 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claims 27 and 36 are representative and read as follows:

27. A therapeutic composition comprising (a) a physiologically acceptable solution or buffer, (b) an antigen presenting cell, and (c) an immunostimulatory cytokine or a nucleic acid encoding an immunostimulatory cytokine, wherein the antigen presenting cell is not loaded or pulsed with antigens.

36. A therapeutic composition comprising (a) a pharmaceutically acceptable carrier, (b) an antigen presenting cell, and (c) an immunostimulatory cytokine or a nucleic acid encoding an immunostimulatory cytokine, wherein the antigen presenting cell is not loaded or pulsed with antigens.

Issue

The Examiner has rejected all of the claims on appeal under 35 U.S.C. § 102(b) as anticipated by both Bhardwaj[2] (with evidence provided by Hackstein[3]) and Kelleher[4] (Answer 3-4). Because the same issue is dispositive with respect to both rejections, we will address them together.

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[2] Nina Bhardwaj et al., *IL-12 in Conjunction with Dentritic Cells Enhances Antiviral CD8+ CTL Responses in Vitro*, 98 J. OF CLIN. INVESTIGATION 715-722 (1996).

[3] Holger Hackstein et al., *Rapamycin inhibits macropinocytosis and mannose receptor-mediated endocytosis by bone marrow-derived dendritic cells*, 100 BLOOD 1084-1087 (2002).

The Examiner finds that both Bhardwaj and Kelleher disclose a composition comprising antigen presenting cells (specifically, dendritic cells), IL-12, and cell culture medium (Answer 3-4). The Examiner finds that the cell culture medium in the prior art compositions "meets the limitations of a 'physiologically' or 'pharmaceutically' acceptable buffer and a 'therapeutic composition'" (*id.*).

Appellants contend that the recitation of a "therapeutic composition" in the preambles of the claims limits the claimed compositions (Appeal Br. 3-4; Reply Br. 2-3) and distinguishes them from the compositions disclosed in the prior art (Appeal Br. 5-7; Reply Br. 4-5).

The issue presented in this appeal is: Does the broadest reasonable interpretation of the claim language encompass the cell culture compositions disclosed by Bhardwaj and Kelleher?

Findings of Fact

1. We adopt the Examiner's findings regarding the scope and content of Bhardwaj and Kelleher (Answer 3-4).

2. The Specification states:

> The formulations, both for veterinary and for human medical use, of the DCs [dendritic cells] and cytokines . . . typically include such drugs in association with a pharmaceutically acceptable carrier. . . . The carrier(s) should be "acceptable" in the sense of being compatible with the other ingredients or cells of the formulations and not deleterious to the recipient thereof. Pharmaceutically acceptable carriers . . . are intended to include

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[4] Peter Kelleher et al., *IL-12 increases CD80 expression and the stimulatory capacity of bone marrow-derived dendritic cells*, 10 INTERNATIONAL IMMUNOLOGY 749-755 (1998).

> any and all solvents, dispersion media, coatings, antibacterial and antifungal agents, isotonic and absorption delaying agents, and the like, compatible with pharmaceutical administration.

(Spec. 18, ¶ 46.)

3. The Specification states that a "pharmaceutical composition of the invention should be formulated to be compatible with its intended route of administration. Examples of routes of administration include oral or parenteral, e.g., intravenous, intraarterial, intradermal, intratumoral, inhalation, transdermal (topical), transmucosal, and rectal administration." (*Id.* at 18, ¶ 47.)

4. The Specification states that "[i]n a preferred embodiment, the DCs and cytokines . . . are administered in AIM5 medium or other medium compatible with the viability and activity of the DCs" (*id.*).

Analysis

Appellants do not dispute that the compositions disclosed by Bhardwaj and Kelleher include each of the components recited in the body of claims 27 and 36. The only issue on appeal is whether the recitation of a "therapeutic composition" in the claims' preambles limits the claimed compositions in a way that distinguishes them from the prior art compositions.

Appellants have not pointed to any express definition of "therapeutic composition" in the Specification but cite the Declaration of Michael T. Lotze (filed under 37 C.F.R. § 1.132, dated June 29, 2007) as evidence that those of skill in the art would not consider a "therapeutic composition" to encompass the cell culture compositions of Bhardwaj and Kelleher (Appeal Br. 5; Reply Brief 4).

> Dr. Lotze declared that
>
> [p]hysicians and medical researchers would not understand Bhardwaj and Kelleher to disclose a "therapeutic composition." . . . Nothing in these references suggests that the cell cultures have any therapeutic value. The cultures were simply used to investigate the role of IL-12. Accordingly, a physician reading Bhardwaj and Kelleher would not consider their cell cultures to be "therapeutic compositions."

(Lotze Declaration, ¶ 9.)

Dr. Lotze's reasoning does not persuade us that the Examiner's claim interpretation is unreasonably broad. Dr. Lotze's conclusion is based on the facts that the prior art did not disclose that the cell culture compositions had any therapeutic value and did not use them in therapy. However, the claims are directed to compositions, not methods. *See Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990) ("[A]pparatus claims cover what a device *is*, not what a device *does*."). As with apparatus claims, claims to a composition cover what the composition is, not what it does. The fact that Bhardwaj and Kelleher did not disclose that their compositions could be used in therapy does not establish that they are not suitable for such use; the prior art compositions are therefore within the broadest reasonable interpretation of a "therapeutic composition."

Dr. Lotze also declared that "a physician would not consider the cell cultures of Bhardwaj and Kelleher to be suitable for use [as] 'therapeutic composition[s]'" because "[t]hese raw cell cultures would contain contaminants and impurities that may cause potentially serious reactions in patients. Many components of raw cell cultures have inhibitory proteins that are known, such as IL10 or TGFβ, or other elements which are unknown." (Lotze Declaration, ¶ 10.)

This reasoning also does not persuade us that the Examiner's claim construction is in error. Dr. Lotze identifies only IL10 and TGFβ as potentially problematic components of the prior art compositions but, as the Examiner has pointed out (Answer 5), those cytokines are expressly recited in claim 31 and are therefore not excluded from the claimed composition. Dr. Lotze did not point to any other specific component in either prior art composition that would preclude its use in therapy.

In short, Appellants have pointed to no evidence of record, in the Lotze Declaration or otherwise, showing that the compositions disclosed by Bhardwaj and Kelleher would not be suitable for, e.g., oral or topical administration. The Specification in fact states that one preferred embodiment of the disclosed invention is administration "in AIM5 medium or other medium compatible with the viability and activity of the DCs" (FF 4). Bhardwaj and Kelleher disclose culturing dendritic cells in their media (Bhardwaj 719, legend to Table 1; Kelleher 749-750). Each of the prior art compositions therefore reasonably appears to be a "medium compatible with the viability and activity of the DCs" and thus suitable for pharmaceutical administration.

Conclusion of Law

The broadest reasonable interpretation of the claim language encompasses the cell culture compositions disclosed by Bhardwaj and Kelleher.

SUMMARY

We affirm both of the rejections on appeal.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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